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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,908	10/23/2000	Paul L. Hermonat	023533/0130	8355

7590 09/10/2002

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/10/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,908	Applicant(s) HERMONAT, PAUL L.
	Examiner Billy D Chism	Art Unit 1653

-- The MAILING DATE of this communication app a rs on th e cover she et with th e correspondenc e address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____ .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-20, 46 and 47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-20, 46 and 47 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) Interview Summary (PTO-413) Paper No(s). _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

This Office Action is in response to the Paper # 11, filed 28 June 2002, wherein Applicants canceled claims 1 and 21-45 without prejudice or disclaimer. Claims 2-20 and 46-47 are now under consideration by the examiner.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

Claim Rejections and Objections (New and/or Maintained)

Specification

The abstract of the disclosure is objected to because the abstract is in excess of 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New--Claim 2 (New is indefinite as to what is the "corresponding wild-type AAV Rep 78." It is noted that the response filed 27 June 2002, at page 5 refers to pages 2 and 19 of the specification as definition, however, the instant page of the specification does not appear to define the AAV Rep 78 protein (by structure/sequence) against which all modifications are assessed. No reference sequence for the wild-type Rep 78 is apparent. Note that claim 2 includes as currently presented, a dipeptide of AAV Rep 78 that has DNA binding.

Maintained--Claim 2 remains rejected for the indefinite recitation of "binds...differently" which can be interpreted in two ways. Binding differently can be interpreted as binding at a different site/location or to have a different binding affinity as is indicated in subsequent claim 3 wherein the different binding is indicated to be no binding, weak binding or enhanced DNA binding. Although Applicant has indicated where to find the support for this in the specification, the response from Applicant does not obviate the ambiguity of the wording in the claim. Applicant should consider combining claims 2 and 3, or amending claim 2 to recite the limitation that the mutant/modified protein has different binding affinities, which finds support in the specification on page 2, line 19.

New—Claim 46 is rejected for depending from rejected claim 2.

Maintained--The rejection of Claim 7 as indefinite for recitation of "minimum number of amino acids" is maintained. Applicant stated that the specification discloses assays to determine binding of the AAV Rep 78 proteins to DNA and that the specification states that the process would not impose undue experimentation for one skilled in the art to elucidate the minimum number of amino acids to obtain enhanced inhibition. However, stating the ability of one skilled in the art does not make the claim, *per se*, definite as to the metes and bounds of the claim nor

define how many and what amino acids are present. The truncation mutation can be any one or more of any of singular or multiple substitutions, deletions, or insertions or single or multiple combinations thereof. Neither the protein nor the mutant is defined by structure in the claim; thus, there is a myriad of starting points and ending points, and while broad, does not define uniquely the claimed peptide in a manner ascertainable by the skilled artisan.

New--Claims 13-20 and 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the reasons given in the Maintenance of Rejections above, Claim 13 is rejected as indefinite for the recitation of "bind...differently." Claims 14-18 and 47 are rejected for depending from indefinite Claim 13. As explained above, Applicant can overcome this rejection by directing the claim to different binding affinities.

New--Claim 19 is indefinite for the recitation of the term "admxiture" wherein it is not clear if the admixture is of equal or unequal amounts. This can be overcome by omitting the term "admxiture" as it is understood that the composition would comprise some mixture of the protein and a pharmaceutical carrier.

New--Claims 13 and 19 are indefinite wherein an "AAV Rep 78 protein" is claimed. The examiner has considered all claims, insofar as elected subject matter is concerned, to be drawn to AAV Rep 78 mutant/modified proteins; thus, the pharmaceutical composition of Claim 19 will only be considered as being drawn to "at least one AAV Rep 78 mutant according to claim 2", an AAV Rep 78 modified protein. Furthermore, Claim 13 will only be considered wherein the composition comprises an AAV Rep 78 modified/mutant protein, and will not be considered as comprising a wild-type AAV Rep 78 protein. The examiner views the inclusion of comprising a

wild-type AAV Rep 78 protein as reading on non-elected subject matter for it is considered to be another invention.

For the reasons stated above, Applicant's arguments against the 35 U.S.C. 112, second paragraph, rejections against claims 2-12 are maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2-20 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for AAV Rep 77^{LG}, 79^{FA} and 192^{HG} modified proteins, does not reasonably provide enablement for other mutants and/or modified proteins of the AAV Rep 78 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does give guidance as to how AAV Rep 77^{LG}, 79^{FA} and 192^{HG} modified proteins were prepared. However, the specification does not give guidance as to how other AAV Rep 78 modified proteins would be made and used, since it would require the exercise of undue experimentation for one of skill in the art to assess all possible mutants and/or modified proteins which include; single or multiple substitutions, deletions, or insertions or single or multiple combinations thereof. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in

determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention and the breadth of the claims,

In the instant case, Applicant is claiming AAV Rep 78 mutants comprising AAV Rep 78 modified proteins.

2. the state of the prior art, the predictability or lack thereof in the art,

The prior art, as taught by Batchu *et al.* 1995 (Biochemical and Biophysical Research Communications, Vol. 210, No.3: 771-725) (cited in Paper No. 10, filed 25 March 2002), teaches a modified AAV Rep 78 protein that lacks the ability to bind DNA and it lacks the ability to replicate; thus, even though Applicant teaches one modified protein that results in DNA binding and replication, there is no predictability within the art that would allow a skilled artisan to know if any one of the many possible mutant/modified AAV Rep 78 proteins claimed by Applicant would result in DNA binding and replication as is interpreted by the claims.

3. the amount of direction or guidance present, the presence or absence of working examples,

Although Applicant discloses guidance for making AAV Rep 77^{LG}, wherein the skilled artisan could also make and use AAV Rep 192^{HG} and 79^{FA}, Applicant has not disclosed any working examples that would demonstrate, or guide, skilled artisan as to how the AAV Rep 78 mutants comprising AAV Rep 78 modified proteins, other than those disclosed, were prepared or obtained.

6. the quantity of experimentation needed, and the level of the skill in the art.

The wild-type AAV Rep 78 and any one or more of any singular or multiple substitutions, deletions, or insertions or single or multiple combinations thereof are possible, and place undue experimentation on one skilled in the art. The specification must teach how to make the invention, and the specification is enabled for the making of the above specifically discussed AAV Rep 78 modified proteins, however, the specification is not enabled for the myriad of other possible AAV Rep 78 modified proteins. *In re Gardner*, 166 U.S.P.Q. 138 (1970). In order to practice the claimed invention, one skilled in the art would need to speculate how the AAV Rep 78 modified proteins were obtained or prepared. Therefore, the instant invention is not enabled.

Conclusion

No claims allowed. All points in Applicant's response are addressed herein and it should be noted that this action is Non-Final due to the new grounds for rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
09 September 2002

Christopher S. F. Low
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